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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Dorothy B. Franks et al.

Serial No.: 09/620,520

Filed: July 20, 2000

For: AUTOMATIC IDENTIFICATION
OF MEDICAL STAFF TRAINING
NEEDS

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Group Art Unit: 3714

Examiner: Mosser, Kathleen Michele

Atty. Docket: GEMS:0091/YOD/SWA
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L. Lee Eubanks IV

APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 41.31 AND 41.37

This Appeal Brief is being filed in furtherance to the Notice of Appeal mailed on November 14, 2006, and received by the Patent Office on November 17, 2006.

Appellants note that two fees for previous Appeal Briefs have already been paid with respect to this application, including a fee of \$500.00 for the Appeal Brief filed on April 5, 2005. Further, neither of the previous appeals resulted in a final Board decision. In accordance with M.P.E.P. § 1204.01, Appellants respectfully note that the fee paid for the previous Appeal Brief should be applied to the instant Appeal Brief, and believe that no additional fee is due for the present filing. However, should any additional fees be required to advance prosecution of the present application, the Commissioner is authorized to charge such additional fees to Deposit Account No. 50-2402; Order No. 15-SV-5495/YOD (GEMS:0091). In accordance with 37 C.F.R. § 1.136, Appellants hereby provide a general authorization to treat this and any future reply requiring an extension of time as incorporating a request therefor. Furthermore, Appellants authorize the Commissioner to charge the appropriate fee for any extension of time to Deposit Account No. 50-2402; Order No. 15-SV-5495/YOD (GEMS:0091).

1. **REAL PARTY IN INTEREST**

The real party in interest is GE Medical Technology Services, Inc., which is the Assignee of the above-referenced application by virtue of the Assignment recorded at reel 011193, frame 0029, and recorded on October 16, 2000. GE Medical Technology Services, Inc., the Assignee of the above-referenced application, as evidenced by the document mentioned above, will be directly affected by the Board's decision in this Appeal.

2. **RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any other appeals or interferences related to this appeal. The undersigned is Appellants' legal representative in this appeal.

3. **STATUS OF CLAIMS**

Claims 1-7 and 9-28 are currently pending, are currently under final rejection, and are the subject of this appeal. Claim 8 was previously canceled by Appellants and is not subject to the instant appeal.

4. **STATUS OF AMENDMENTS**

The instant claims have not been amended subsequent to the Final Office Action mailed September 14, 2006. Consequently, there are no outstanding amendments to be considered by the Board.

5. **SUMMARY OF CLAIMED SUBJECT MATTER**

The present invention relates generally to the field of medical institutions and services and, more specifically, to techniques for identifying potential service personnel training needs. *See, e.g.*, Application, page 1, lines 6-9. The present application contains four independent claims, namely claims 1, 15, 23, and 28, all of which have been improperly rejected and, thus, are subject to this appeal. The subject matter of the independent claims is summarized below.

With regard to the aspect of the invention set forth in independent claim 1, discussions of the recited features of claim 1 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to a method of identifying training needs for biomedical equipment in a medical institution (e.g., 12, 14, 16). *See, e.g.*, Application, page 4, lines 17-19; FIG. 1. The method includes collecting (e.g., 74, 78, 88, 92) identification and operation data associated with a plurality of biomedical equipment components and storing (e.g., 94) the collected data in a central database (e.g., 36, 60). *See, e.g., id.* at page 5, lines 16-24; page 7, lines 4-9; page 7, line 17 – page 8, line 13; FIGS. 1 and 2; *see also, e.g., id.* at page 5, line 26 – page 6, line 8. The method also includes analyzing (e.g., 76, 118, 184, 186) the operation data to identify at least one operational parameter (e.g., logged errors, downtimes, service inquiries, procedural inquiries or the like) affected by operator activities with the equipment components. *See, e.g., id.* at page 9, line 9 – page 10, line 4; page 10, line 19 – page 11, line 10; page 14, line 28 – page 15, line 4; FIGS. 2, 4, and 6-9. Further, the method includes identifying (e.g., 188) a training need based on the analyzed operational parameter and outputting (e.g., 190, 200) a report indicating the identified training need. *See, e.g., id.* at page 15, lines 4-31; FIGS. 9 and 10.

With respect to the aspect of the invention set forth in independent claim 15, discussions of the recited features of claim 15 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to a system for identifying training needs associated with a plurality biomedical equipment components in a medical institution (e.g., 12, 14, 16). *See, e.g., id.* at page 4, lines 17-19; FIG. 1. The system includes a central database (e.g., 36, 60) configured to store data representative of the equipment components, the stored data including operation data and identification data identifying at least an equipment type. *See, e.g., id.* at page 5, lines 16-24; page 7, lines 4-9; page 7, line 17 – page 9, line 7; FIGS. 1 and 2. The system also includes a data analysis module (e.g., 76, 118) configured to arrange the operation data into groupings and to analyze the

operation data based on the groupings, the groupings including an equipment type grouping. *See, e.g., id.* at page 9, line 9 – page 11, line 10; page 12, line 19 – page 13, line 17; FIGS. 2 and 4. Additionally, the system includes a report generator (e.g., 124) configured to generate a report (e.g., 138) including an arrangement of the analyzed operation data based on the groupings, wherein a training need is identifiable based on the arrangement. *See, e.g., id.* at page 11, line 7 – page 12, line 17; page 14, line 28 – page 15, line 31; FIGS. 2, 4, and 6-10.

Regarding the aspect of the invention set forth in independent claim 23, discussions of the recited features of claim 23 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to a method for identifying a training need associated with biomedical equipment in a medical institution (e.g., 12, 14, 16). *See, e.g., id.* at page 4, lines 17-19; FIG. 1. The method includes storing (e.g., 94) data associated with the equipment in a central database (e.g., 36, 60), the stored data including equipment operation data and equipment identification data, and grouping (e.g., 96) the stored equipment operation data in accordance with the corresponding equipment identification data. *See, e.g., id.* at page 5, lines 16-24; page 7, lines 4-9; page 7, line 17 – page 9, line 7; FIGS. 1 and 2. The method further includes analyzing (e.g., 150) the equipment operation data based on the grouping and generating (e.g., 158) a presentation of the analyzed equipment operation data in accordance with the grouping. *See, e.g., id.* at page 9, line 9 – page 11, line 10; page 12, line 28 – page 13, line 17; FIG. 5. Also, the method includes identifying (e.g., 188) a training need associated with a particular piece of equipment based on the presentation and outputting (e.g., 190, 200) a report indicating the identified training need. *See, e.g., id.* at page 15, lines 4-31; FIGS. 9 and 10.

Finally, with respect to the aspect of the invention set forth in independent claim 28, discussions of the recited features of claim 28 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to a system for of identifying training needs

for biomedical equipment in a medical facility (e.g., 30, 32, 34). *See, e.g., id.* at page 5, lines 1-13; FIG. 1. Appellants note that claim 28 recites elements described in means-plus-function language as permitted by 35 U.S.C. § 112, sixth paragraph, and that each of the recited elements should be interpreted in accordance with this body of law. The system includes means for collecting (e.g., 74, 78, 88, 92) identification and operation data associated with a plurality of biomedical equipment components and means for storing (e.g., 94) the collected data in a central database (e.g., 36, 60). *See, e.g., id.* at page 5, lines 16-24; page 7, lines 4-9; page 7, line 17 – page 8, line 13; FIGS. 1 and 2; *see also, e.g., id.* at page 5, line 26 – page 6, line 8. As discussed in the specification, the means for collecting include a network interface (e.g., 70), while the means for collecting and the means for storing each include a database (e.g., 36, 60), server (e.g., 66), or some other device having one or more applications (e.g., 62) for providing such functionality. *See, e.g., id.* at page 6, line 24 – page 7, line 15; FIG. 1. The system also includes means for analyzing (e.g., 76, 118, 184, 186) the operation data to identify at least one operational parameter (e.g., logged errors, downtimes, service inquiries, procedural inquiries or the like) affected by operator activities with the equipment components. *See, e.g., id.* at page 9, line 9 – page 10, line 4; page 10, line 19 – page 11, line 10; page 14, line 28 – page 15, line 4; FIGS. 2, 4, and 6-9. The disclosed means for analyzing include a database (e.g., 36, 60), server (e.g., 66), or some other device having one or more applications (e.g., 62), including an analysis module (e.g., 118), for providing such functionality. *See, e.g., id.* at page 6, line 24 – page 7, line 15; page 10, line 16 – page 11, line 10; FIGS. 1 and 4. Finally, the system includes means for identifying (e.g., 188) a training need based on the analyzed operational parameter. *See, e.g., id.* at page 15, lines 4-11; FIG. 9. The disclosed means for identifying include a database (e.g., 36, 60), server (e.g., 66), or some other device having one or more applications (e.g., 62) for providing such functionality. *See, e.g., id.* at page 6, line 24 – page 7, line 15; FIG. 1.

6. **GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

Sole Ground of Rejection for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the Examiner's sole ground of rejection in which the Examiner rejected claims 1-7 and 9-28 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

7. **ARGUMENT**

As discussed in detail below, the Examiner has improperly rejected the pending claims. Further, the Examiner has misapplied long-standing and binding legal precedents and principles in rejecting the claims under 35 U.S.C. § 112, first paragraph. Accordingly, Appellants respectfully request full and favorable consideration by the Board, as Appellants strongly believe that claims 1-7 and 9-28 are currently in condition for allowance.

As one skilled in the art will appreciate, the need for training in medical facilities is particularly apparent due to the wide range of existing biomedical equipment systems and due to the continual, and sometimes rapid, evolution of these biomedical equipment systems. *See, e.g., id.* at page 1, lines 13-23. Typically, personnel utilize *existing* training mechanisms at *predefined* times. For example, personnel generally receive training at the time of initial employment, at the time of purchasing new biomedical equipment systems, and at conferences. *See, e.g., id.* at page 1, lines 25-29. Personnel also may review various texts, journals, and other readily available materials. *See, e.g., id.* Unfortunately, these techniques do not adequately address specific training needs of clients and their use of biomedical equipment systems. *See, e.g., id.* at page 1, line 29 – page 2, line 4. One major problem associated with these training techniques is the *lack of any feedback* to ensure the appropriate time, amount, focus, and type of training materials. *See, e.g., id.* at page 2, line 1 – page 3, line 9. Without such feedback, the training techniques may be untimely, insufficient, misdirected, and improper for the particular equipment, personnel, and scenario. As a consequence, the medical diagnosis and treatment provided by personnel operating the biomedical equipment systems may be

less accurate than desired, and improper operation of such equipment may result in equipment damage and generally poor utilization of biomedical equipment systems.

The present claims generally target the drawbacks of conventional training techniques by monitoring, collecting, grouping, analyzing, and/or reporting data relating to biomedical equipment and one or more medical institutions. *See, e.g., id.* at page 4, lines 15-17; page 7, lines 17-23; page 8, lines 19-28. For example, the data may comprise equipment data (e.g., inventory, operational history, performance, etc.), service data (e.g., service contracts, warranties, service history, etc.), and personnel data. *See, e.g., id.* at page 4, lines 22-25; page 8, line 22 – page 9, line 7; page 14, lines 8-11 and 28-31; page 15, lines 7-11. It is important to point out that the claimed subject matter of the present application is not a mere data monitoring and collection technique, but rather the system 10 actively and logically groups, processes, and analytically generates results targeting equipment performance and training *needs* of personnel. *See, e.g., id.* at page 9, lines 9-28; page 10, lines 23-31; page 12, lines 19-26; page 13, lines 2-6 and 11-16; page 14, line 28 – page 15, line 11. Moreover, the disclosed system 10 does not merely distribute preexisting training materials, but rather the system 10 analyzes the acquired data to provide *feedback-based control of personnel training* for the biomedical equipment systems. *See, e.g., id.* at page 3, lines 2-9; page 14, line 28 – page 15, line 11. As a result, the system 10 actively improves training techniques to enhance the overall performance and use of the biomedical equipment systems. *See, e.g., id.*

Sole Ground of Rejection:

Turning now to the first and only ground of rejection of the instant claims, the Examiner improperly rejected claims 1-7 and 9-28 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. Because this rejection is factually and legally deficient, and directly contrary to previous binding precedent of the Federal Circuit, Appellants respectfully traverse this rejection.

Regarding the enablement requirement, the Examiner has the initial burden to establish a *reasonable basis* to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). The test for enablement, as set forth by the Supreme Court, is whether the experimentation needed to practice the invention is undue or unreasonable. *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991). The *undue experimentation* test essentially evaluates whether one of reasonable skill in the art can make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *U.S. v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988). As long as the specification discloses at least one method for making and using the claimed invention that bears a *reasonable correlation* to the entire scope of the claim, then the enablement requirement of section 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (C.C.P.A. 1970).

In the Office Action, the Examiner specifically stated:

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. Claim 1 includes the limitation “analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment component”. Similar limitations occur in each of independent claims 15, 23 and 28, and are incorporated into the dependent claims through their dependencies. The specification fails to teach how the operational parameters can [be] used to make such identifications. Although the specification mentions several operational parameters that may be used in the analysis, it does not show what types of operators activities may cause an effect on these parameters or how the analysis is to actually be performed. Deriving such algorithms and determining how each parameter is [a]ffected by operators’ activities would require *undue experimentation* on the part of one of ordinary skill in the

art. Further, claim 5 recites that the data is representative of individual operators utilizing the equipment components. The specification makes no mention as to how the specific user of a piece of biomedical equipment is tracked or determined.

Office Action mailed September 14, 2006, page 2 (emphasis added). Despite the Examiner's apparent confusion, Appellants respectfully submit that one of ordinary skill in the art would be able to practice the presently disclosed invention based on the specification of the instant application, coupled with information known in the art, without undue experimentation.

As previously noted, the present application is generally directed to identifying potential training needs of service personnel. Application, page 1, lines 7-9. Among other things, Appellants have disclosed a service system 10 that facilitates identification of certain training needs based on various data. *See id.* at page 4, lines 15-17; FIG. 1. In one embodiment, the system 10 includes various hardware components, such as databases 60 and servers 66, and various modules for collecting, storing, and analyzing data, such as data collection/storage/association sequence 74, population data sequence 76, and analysis module 118. *See, e.g., id.* at page 7, lines 6-21; page 10, lines 19-22; FIGS. 1, 2, and 4. In an exemplary embodiment, specific data obtained from a specific institution may be analyzed by comparison to a benchmark derived from other institutions or groups of such institutions. *See id.* at page 9, line 9 – page 10, line 4; page 10, line 23 – page 11, line 10. Analysis of the data may also include determination of utilization parameters, identification of error codes, trends, and so forth, and also identification of trends in the data over time. *See id.* at page 12, line 28 – page 13, line 6. In this exemplary embodiment, training needs may be identified in areas in which the specific institutional data deviates substantially from the benchmark data, or training needs may be identifiable to one skilled in the art based on logged errors, downtimes, and service or procedural inquiries. *See id.* at page 13, lines 8-16; page 14, lines 23 – page 15, line 11.

Claims 1-4, 6-14, and 28

Regarding claims 1-4, 6-14, and 28, Appellants respectfully submit that independent claim 1 is representative of this group. The Examiner rejected these claims, arguing that the recitation of “analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment components” is not enabled. *See* Office Action mailed September 14, 2006, page 2. With particular regard to this element, the Examiner’s factual and legal analysis appears to consist entirely of:

The specification fails to teach how the operational parameters can [be] used to make such identifications. Although the specification mentions several operational parameters that may be used in the analysis, it does not show what types of operators activities may cause an effect on these parameters or how the analysis is to actually be performed. Deriving such algorithms and determining how each parameter is [a]ffected by operators’ activities would require *undue experimentation* on the part of one of ordinary skill in the art.

See id.

As an initial matter, Appellants respectfully submit that this element is *self-enabling*, i.e., that one of ordinary skill in the art, based on the claim language and information known in the art, would be capable of analyzing operational data and identifying an operational parameter (such as logged errors, downtimes, service inquiries, procedural inquiries or the like) affected by an operator activity with the equipment component. One skilled in the art would certainly recognize that the occurrence and frequency of certain events, such as procedural inquiries or certain error codes, may be directly correlated to operator activities. Further, Appellants find the assertion that a skilled artisan could not analyze data to identify those portions of the data pertaining to error codes, procedural inquiries, or the like to be wholly without merit, and is akin to an assertion that a newspaper editor could not analyze a newspaper to identify the classifieds

or the sports section. The Examiner's failure to provide even a *scintilla* of evidence in support of this conclusory assertion is also noted.

Further, in addition to being self-enabling, the specification provides additional support for this recitation. *See, e.g., id.* at page 7, line 17 – page 10, line 4 (providing for the collection, storage, benchmarking, and profiling of data); page 10, line 19 – page 11, line 10 (providing for the analysis of data); page 14, line 28 – page 15, line 4 (providing for identification of potential training needs); FIGS. 2, 4, and 6-9. The present rejection appears to be further based on an assertion that the specification fails to mention [exactly] how the data is analyzed, correlated or used to identify such operational parameters. *See* Office Action mailed September 14, 2006, page 2 (“it does not show ... how the analysis is to actually be performed”), page 4. Appellants are unsure as to the level of specificity the Examiner believes is required. Given that one of ordinary skill in the art would be able to perform such an analysis, as discussed above, the Examiner appears to be requiring more (i.e., explanation sufficient to remove any of her confusion) than is actually required by law (i.e., whether one of ordinary skill in the art can make or use the invention from the patent disclosure *coupled with information known in the art* without undue experimentation). *See U.S. v. Telectronics, Inc.*, 857 F.2d at 785, 8 U.S.P.Q.2d at 1223; *In re Buchner*, 929 F.2d at 661, 18 U.S.P.Q.2d at 1332 (Fed. Cir. 1991) (that a patent need not teach, and preferably omits, what is well known in the art). For these reasons, Appellants respectfully submit that the Examiner has not provided a reasonable basis for challenging the enablement of the recitation of “analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment components” in the instant claims.

In responding to Appellants previous arguments, the Examiner also stated that:

This citation does not show how the data is analyzed, correlated or used to identify “at least one operational parameter affected by operator activities with the equipment component”, as is recited in the claim. Or how such an identification is then used to determine a training

need based on the analyzed data. It is unclear how data relating to logged errors, downtimes, and service and procedural inquiries equity to use *[sic]* parameters affected by operator activities with the equipment component, when related to the use of biomedical equipment.

Office Action mailed September 14, 2006, page 4 (emphasis added). Appellants respectfully submit that, despite the Examiner's apparent confusion, one of ordinary skill in the art upon reading the instant disclosure would immediately appreciate that *operational parameters such as the disclosed "logged errors, downtimes, service and procedural inquiries," and the like may result from operator activities of the biomedical equipment components*. Further, through analysis of such operational parameters (e.g., repeated logged errors, procedural inquiries, or the like), one of ordinary skill in the art would be able to identify training needs with respect to the equipment components (e.g., excessive procedural inquiries with respect to a particular system would indicate a training need for users of that system).

As will be appreciated by those of ordinary skill in the art, the level of specificity of the training need (e.g., system-wide, process-specific, component-specific, and so forth) may depend upon the quantity and type of the identified operational parameters. For instance, logged errors may specifically indicate the exact nature and cause of errors (user error vs. hardware/software error), or may only indicate that errors have occurred. In the case of the latter, one of ordinary skill in the art having benefit of the present disclosure would be able to correlate the occurrence of a large number of errors in one system (which may be measured in comparison to the population/benchmark data disclosed in the present application) with the existence of a general training need with respect to users of that system. Conversely, with respect to the former, one of ordinary skill in the art would be able to correlate more specific logged errors with more particular training needs. Again, Appellants respectfully submit that performing such analysis and identification steps are well within the abilities of one of ordinary skill in the art, and the Examiner has presented no objective evidence to the contrary in support of the present rejection.

Still further, Appellants respectfully submit that, at a minimum, a *prima facie* case with respect to non-enablement requires the Examiner to conduct a *factual* analysis and provide sufficient *evidence* that a disclosure does not satisfy the enablement requirement *and* that any necessary experimentation is “undue.” See M.P.E.P. § 2164 *et seq.* The rejection set forth in the Office Action, however, fails to make such an analysis or provide such evidence. In essence, the rejection is conclusory – alleging that undue experimentation would be required of one of ordinary skill in the art, without *any* analysis or evidence with respect to the level of one of ordinary skill or explanation why any experimentation would be “undue.” Appellants note that “[t]he fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation.” M.P.E.P. § 2164.01; *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int’l Trade Comm’n 1983), *aff’d sub nom.*, *Massachusetts Institute of Technology v. A.B. Fortia*, 227 U.S.P.Q. 428 (Fed. Cir. 1985). Further, Appellants again point out that although development of an actual implementation of the present claims may require various implementation-specific decisions to achieve certain goals, such development would be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill in the art having the benefit of this disclosure, and would not require undue experimentation. Appellants respectfully submit that the present rejection, which lacks legally sufficient analysis and evidence, and provides *no* rationale as to why any experimentation the Examiner believes necessary would be undue, cannot establish a *prima facie* case of non-enablement, and is facially improper.

For at least the reasons provided above, Appellants respectfully request that the Board withdraw the improper rejection of claims of 1-4, 6-14, and 28 under 35 U.S.C. § 112, first paragraph. Additionally, Appellants respectfully request that the Board direct the Examiner to allow the instant claims.

Claim 5

Appellants respectfully note that claim 5 depends from independent claim 1. Further, Appellants refer the Board to the discussion provided above with respect to independent claim 1, which is incorporated herein by reference. Claim 5 recites, in relevant part, “wherein the data includes data representative of individual operators utilizing the equipment components.” The Examiner challenged the enablement of the subject matter of dependent claim 5, stating that “the specification makes no mention as to how the specific user of a piece of biomedical equipment is tracked or determined.” Office Action mailed September 14, 2006, page 2. Appellants respectfully submit that, as one of even rudimentary skill in the art would appreciate, specific users of biomedical equipment, such as imaging systems, patient monitors, or the like, may be tracked through an authentication procedure (e.g., logging-on to a system). Because such tracking is notoriously well known in the art, Appellants respectfully submit that the subject matter explicitly recited in claim 5 is self-enabling. Accordingly, for this reason, in addition to those provided above, Appellants respectfully request that the Board withdraw the improper rejection of claim 5 under 35 U.S.C. § 112, first paragraph, and direct the Examiner to allow the present claim.

Claims 15-22

Regarding claims 15-22, Appellants respectfully submit that independent claim 15 is representative of this group. Independent claim 15 recites:

15. A system for identifying training needs associated with a plurality biomedical equipment components in a medical institution, the system comprising:

a central database configured to store data representative of the equipment components, the stored data including operation data and identification data identifying at least an equipment type;

a data analysis module configured to arrange the operation data into groupings and to analyze the operation data based on the groupings, the groupings including an equipment type grouping; and

a report generator configured to generate a report including an arrangement of the analyzed operation data based on the groupings, wherein a training need is identifiable based on the arrangement.

As noted above, the Examiner rejected this claim for allegedly failing to comply with the enablement requirement. However, in the Office Action, this claim was simply grouped by the Examiner with independent claim 1 and was not substantively addressed. *See* Office Action mailed September 14, 2006, page 2. To the extent that certain recitations of claim 1 and 15 overlap, in whole or in part, Appellants refer to the arguments provided above with respect to independent claim 1, which are incorporated by reference herein.

However, Appellants respectfully submit that, due to substantial differences between the recitations of claims 1 and 15, it is unclear how the Examiner's apparent confusion with respect to claim 1 is applicable to claim 15. Particularly, with respect to claim 1, the Examiner seems primarily concerned with the "identify at least one operational parameter affected by operator activities with the equipment components," while claim 15 does not contain such a recitation. In the interest of advancing the present case, Appellants respectfully submit that the recitations of this claim are supported by at least the following portions of the present specification in combination with the common knowledge of one skilled in the art, including: "a central database configured to ..." (*see, e.g.*, Application at page 5, lines 16-24; page 7, lines 4-9; page 7, line 17 – page 9, line 7; FIGS. 1 and 2), "a data analysis module configured to ..." (*see, e.g., id.* at page 9, line 9 – page 11, line 10; page 12, line 19 – page 13, line 17; FIGS. 2 and 4), and "a report generator configured to..." (*see, e.g., id.* at page 11, line 7 – page 12, line 17; page 14, line 28 – page 15, line 31; FIGS. 2, 4, and 6-10).

Because the rejection fails to provide an adequate legal or factual basis for challenging the sufficiency of the disclosure, or provide any evidence as to why any necessary experimentation would be undue, a *prima facie* case of non-enablement of claims 15-22 has not been established. For at least these reasons, Appellants respectfully

request that the Board withdraw the improper rejection of claims of 15-22 under 35 U.S.C. § 112, first paragraph. Additionally, Appellants respectfully request that the Board direct the Examiner to allow the instant claims.

Claims 23-27

Regarding claims 23-27, Appellants respectfully submit that independent claim 23 is representative of this group. Independent claim 23 recites:

23. A method for identifying a training need associated with biomedical equipment in a medical institution, the method comprising:
- storing data associated with the equipment in a central database, the stored data including equipment operation data and equipment identification data;
 - grouping the stored equipment operation data in accordance with the corresponding equipment identification data;
 - analyzing the equipment operation data based on the grouping;
 - generating a presentation of the analyzed equipment operation data in accordance with the grouping;
 - identifying a training need associated with a particular piece of equipment based on the presentation;
 - and
 - outputting a report indicating the identified training need.

As noted above, the Examiner rejected this claim for allegedly failing to comply with the enablement requirement. However, in the Office Action, this claim (like claim 15) was simply grouped by the Examiner with independent claim 1 and was not substantively addressed. *See* Office Action mailed September 14, 2006, page 2. To the extent that certain recitations of claim 1 and 23 overlap, in whole or in part, Appellants refer to the arguments provided above with respect to independent claim 1, which are incorporated by reference herein.

However, Appellants respectfully submit that, due to substantial differences between the recitations of claims 1 and 23, it is unclear how the Examiner's apparent confusion with respect to claim 1 is applicable to claim 23. Particularly, with respect to claim 1, the Examiner seems primarily concerned with the "identify at least one operational parameter affected by operator activities with the equipment components," while claim 23 does not contain such a recitation. In the interest of advancing the present case, Appellants respectfully submit that the steps recited in this claim are supported at least by the following portions of the specification in combination with the common knowledge of one skilled in the art, including: "storing..." and "grouping..." (*see, e.g.*, Application at page 5, lines 16-24; page 7, lines 4-9; page 7, line 17 – page 9, line 7; FIGS. 1 and 2); "analyzing..." and "generating..." (*see, e.g., id.* at page 9, line 9 – page 11, line 10; page 12, line 28 – page 13, line 17; FIG. 5); and "identifying..." and "outputting..." (*see, e.g., id.* at page 15, lines 4-31; FIGS. 9 and 10).

Because the rejection fails to provide an adequate legal or factual basis for challenging the sufficiency of the disclosure, or provide any evidence as to why any necessary experimentation would be undue, a *prima facie* case of non-enablement of claims 23-27 has not been established. For at least these reasons, Appellants respectfully request that the Board withdraw the improper rejection of claims of 23-27 under 35 U.S.C. § 112, first paragraph. Additionally, Appellants respectfully request that the Board direct the Examiner to allow the instant claims.

Conclusion

In view of the above remarks, Appellants respectfully submit that the Examiner has provided no supportable position or evidence that justifies the present improper rejections of claims 1-7 and 9-28. Consequently, Appellants respectfully submit that all pending claims are in condition for allowance. However, if the Examiner or Board wishes to resolve any other issues by way of a telephone conference, the Examiner or Board is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

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8. **APPENDIX OF CLAIMS ON APPEAL**

Listing of Claims:

1. A method of identifying training needs for biomedical equipment in a medical institution, the method comprising:

collecting identification and operation data associated with a plurality of
biomedical equipment components;

storing the collected data in a central database;

analyzing the operation data to identify at least one operational parameter affected
by operator activities with the equipment components;

identifying a training need based on the analyzed operational parameter; and

outputting a report indicating the identified training need.
2. The method of claim 1, wherein the operational parameter includes operational errors for a type of equipment component.
3. The method of claim 1, wherein the operational parameter includes failures for a type of equipment component.
4. The method of claim 1, wherein the data includes equipment type, and wherein the training need is identified by analyzing the operational parameter for a plurality of equipment components of the equipment type.
5. The method of claim 1, wherein the data includes data representative of individual operators utilizing the equipment components.

6. The method of claim 1, wherein the medical institution includes a plurality of departments, and wherein the data includes data representative of the department to which equipment components are assigned.

7. The method of claim 1, wherein the medical institution includes a plurality of geographically dispersed facility sites, and wherein the data includes data representative of the facility site at which equipment components are located.

9. The method of claim 1, wherein the report is generated at a location remote from the medical institution and is transmitted to the medical institution by a configurable network link.

10. The method of claim 9, wherein the network link includes the Internet.

11. The method of claim 1, comprising the further step of associating the stored data into groups by equipment type, and wherein the training need is identified for an equipment type group.

12. The method of claim 11, further comprising associating the stored data into groups by equipment location, wherein the training need is identified for an equipment type group and an equipment location group.

13. The method of claim 1, wherein the data further identifies an equipment manufacturer for each equipment component, and wherein the training need is identified for equipment components from a particular equipment manufacturer.

14. The method of claim 1, wherein the data further includes data representative of downtime for the equipment components, and wherein the parameter includes downtime.

15. A system for identifying training needs associated with a plurality biomedical equipment components in a medical institution, the system comprising:

a central database configured to store data representative of the equipment components, the stored data including operation data and identification data identifying at least an equipment type;

a data analysis module configured to arrange the operation data into groupings and to analyze the operation data based on the groupings, the groupings including an equipment type grouping; and

a report generator configured to generate a report including an arrangement of the analyzed operation data based on the groupings, wherein a training need is identifiable based on the arrangement.

16. The system of claim 15, wherein the operation data includes breakdowns associated with the equipment components, and wherein the arrangement of the analyzed operation data comprises a presentation of the breakdowns associated with a particular equipment type.

17. The system of claim 15, wherein the operation data includes operator errors associated with the equipment components, and wherein the arrangement of the analyzed operation data comprises a presentation of the operator errors associated with a particular equipment type.

18. The system of claim 15, wherein the arrangement of the operation data includes a first presentation of the operation data for a particular medical facility and a second presentation of the operation data for a plurality of medical facilities.

19. The system of claim 18, wherein the medical facilities are at geographically diverse locations.

20. The system of claim 18, further comprising a user interface configured to provide access to the generated report.

21. The system of claim 20, wherein the report is generated at a location remote from the medical institution and is transmitted to the medical institution via a communication network.

22. The system of claim 21, wherein the communication network includes the Internet.

23. A method for identifying a training need associated with biomedical equipment in a medical institution, the method comprising:

storing data associated with the equipment in a central database, the stored data including equipment operation data and equipment identification data;

grouping the stored equipment operation data in accordance with the corresponding equipment identification data;

analyzing the equipment operation data based on the grouping;

generating a presentation of the analyzed equipment operation data in accordance with the grouping;

identifying a training need associated with a particular piece of equipment based on the presentation; and

outputting a report indicating the identified training need.

24. The method of claim 23, wherein the grouping comprises an equipment type grouping, an equipment manufacturer grouping, and an equipment location grouping.

25. The method of claim 24, wherein the equipment location grouping comprises locations of the pieces of equipment.

26. The method of claim 24, wherein the location grouping references a plurality of geographically diverse medical facilities.

27. The method of claim 23, wherein the operation data includes breakdowns and operator errors associated with the equipment.

28. A system for identifying training needs for biomedical equipment in a medical facility, the system comprising:

means for collecting identification and operation data associated with a plurality of biomedical equipment components;

means for storing the collected data in a central database;

means for analyzing the operation data to identify at least one operational
parameter affected by operator activities with the equipment components;
and
means for identifying a training need based on the analyzed operational
parameter.

9. **APPENDIX OF EVIDENCE**

N/A

10. **APPENDIX OF RELATED PROCEEDINGS**

N/A